



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,321	11/30/1999	ROBERT H. REID	ARMY-103	8870
30951	7590	02/27/2009		
NASH & TITUS, LLC 21402 UNISON RD MIDDLEBURG, VA 20117			EXAMINER MCMILLIAN, KARA RENTTA	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			02/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/451,321

Applicant(s)

REID ET AL.

Examiner

KARA R. MCMILLIAN

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 1-15 are pending in the present reissue application.

Claims 1-15 have previously been identified as allowable.

Claims 16-24 have been canceled by Applicant.

The examiner notes that after an exhaustive review of the present reissue application claims 1-15 are not in condition for allowance. Claims 1-15 are rejected as being dependent upon a defective oath/declaration. Claims 13-15 are rejected under 35 U.S.C. 251 and claim 12 is rejected under 35 U.S.C 112, first and second paragraphs.

The examiner also notes that the next claim set submitted must adequately reflect the status of all of the remaining pending claims including the proper identifiers.

This action is made non-final.

Reissue Applications

Specification (Abstract Objection)

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology

often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure filed on May 16, 1994 is objected to because it is not limited to a single paragraph and contains more than 50 to 150 words. In addition, there is no underlining to add the language. Correction is required. See MPEP § 608.01(b).

The specification filed on May 16, 1994 is further objected to because the cross reference section is improperly formatted.

Oath/Declaration (Objection)

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The latest oath/declaration filed on August 23, 2000 on page 2, paragraph 2, has "We acknowledge the duty to disclose information of which we are aware and which is material to the examination of the application in accordance with 37 C.F.R. §§ 1.56(a) and 1.175(a)(7)." "Examination" should be replaced with "patentability" and 1.56(a)

should be replaced with 1.56. Please use oath form PTO/SB/51 which is an inventor oath.

In addition, the oath/declaration contains crossed out information which has not been initialed (see pages 6 and 7).

Claim Rejections 35 U.S.C. 251

Claims 1-15 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defects in the oath/declaration is set forth in the discussion above in this Office action.

Claims 13-15 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir.1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35

U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In the present case, claims 13-15 of the instant application claim an improvement of a solvent extraction process for preparing microspheres of an agent containing biodegradable polymer comprising preparing a lyophilized agent-stabilizer matrix, adding a solvent to the matrix, preparing a solution of a biodegradable polymer, adding the polymer solution to the matrix solution and adding an oil, centrifuging the emulsion and finally removing the supernatant to obtain the microspheres.

A rejection of original claim 1 in the parent application, 08/242,960, now U.S. Patent No. 5,693,343 was made on July 11, 1995 under 35 USC 112, first paragraph, because the specification, while being enabling for the biodegradable polymer, poly (DL-lactide-co-glycolide) and for the solvent acetonitrile, did not reasonably provide enablement for all biodegradable polymers and solvents. Applicants originally, broadly claimed a solvent extraction process for preparing microspheres comprising, in addition to other steps, adding an antigen-sucrose matrix to any solvent and preparing a solution of any biodegradable polymer by adding the solvent to the polymer as claimed in instant claim 13.

Applicants responded to said rejection on November 13, 1995 by amending claim 1 without traverse to claim the specific biodegradable polymer, poly (DL-lactide-co-glycolide) and the specific solvent, acetonitrile. As applicants have amended original

claim 1 to place said claim in condition for allowance, it is deemed inappropriate for applicants to "recapture" the surrendered subject matter via a reissue procedure.

Furthermore, original claim 1 was also rejected under 35 USC 103 as being unpatentable over Tice et al. (U.S. Patent No. 4,530,840) wherein Tice et al. disclose a process of preparing microspheres containing the biodegradable polymer, poly (DL-lactide-co-glycolide) and organic solvents such as acetone, halogenated hydrocarbons such as chloroform, methylene chloride, etc. In response to said rejection, Applicants amended said claim to recite the specific solvent acetonitrile in the response filed on November 13, 1995. Applicants also argued on page 3 of the response that the process of the instant invention utilizes a different solvent, acetonitrile which does not belong to any of the classes of solvents disclosed and claimed in Tice et al. As applicants have amended original claim 1 to place said claim in condition for allowance, it is deemed inappropriate for applicants to "recapture" the surrendered subject matter via a reissue procedure.

The examiner respectfully points out the following from MPEP 1412.02: A reissue will not be granted to "recapture" claimed subject matter which was surrendered in an application to obtain the original patent. *North American Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 75 USPQ2d 1545 (Fed. Cir. 2005), *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984);

In re Wadlinger, 496 F.2d 1200, 181 USPQ 826 (CCPA 1974); In re Richman, 409 F.2d 269, 276, 161 USPQ 359, 363-364 (CCPA 1969); In re Willingham, 282 F.2d 353, 127 USPQ 211 (CCPA 1960).

"When analyzing a reissue claim for the possibility of impermissible recapture, there are two different types of analysis that must be performed. If the reissue claim "fails" either analysis, recapture exists.

First, the reissue claim must be compared to any claims canceled or amended during prosecution of the original application. It is impermissible recapture for a reissue claim to be as broad or broader in scope than any claim that was canceled or amended in the original prosecution to define over the art. Claim scope that was canceled or amended is deemed surrendered and therefore barred from reissue. In re Clement, *supra*.

Second, it must be determined whether the reissue claim entirely omits any limitation that was added/argued during the original prosecution to overcome an art rejection. Such an omission in a reissue claim, even if it includes other limitations making the reissue claim narrower than the patent claim in other aspects, is impermissible recapture. *Pannu v. Storz Instruments Inc.*, *supra*. However, if the reissue claim recites a broader form of the key limitation added/argued during original prosecution to overcome an art rejection (and therefore not entirely removing that key limitation), then the reissue claim may not be rejected under the recapture doctrine. Ex Parte Eggert, 67 USPQ2d 1716 (Bd. Pat. App. & Inter. 2003) (precedential).

1. Comparison of Reissue Claims Narrowed/Broadened Vis- à-vis the Canceled Claims

DEFINITION: "Canceled claims," in the context of recapture case law, are claims canceled from the original application to obtain the patent for which reissue is now being sought. The claims

(A) can simply be canceled and not replaced by others, or

(B) can be canceled and replaced by other claims which are more specific than the canceled claims in at least one aspect (to thereby define over the art of record). The "replacement claims" can be new claims which are narrower than the canceled claims, or can be the same claims amended to be narrower than the canceled version of the claims.

(a) Reissue Claims are Same or Broader in Scope Than Canceled Claims in All Aspects:

The recapture rule bars the patentee from acquiring, through reissue, claims that are in all aspects (A) of the same scope as, or (B) broader in scope than, those claims canceled from the original application to obtain a patent. In re Ball Corp. v. United States, 729 F.2d at 1436, 221 USPQ at 295.

(b) Reissue Claims are Narrower in Scope Than Canceled Claims in at Least One Aspect:

If the reissue claims are equal in scope to, or narrower than, the claims of the original patent (as opposed to the claims "canceled from the application") in all aspects,

then there can never be recapture. The discussion that follows is not directed to that situation.

It is rather directed to the situation where the reissue claims are narrower than the claims 'canceled' from the application in some aspect, but are broader than the claims of the original patent in some other aspect.

If the reissue claims are narrower in scope than the claims canceled from the original application by inclusion of the limitation added to define the original application claims over the art, there will be no recapture, even if the reissue claims are broader than the canceled claims in some other aspect (i.e., an aspect not related to the surrender made in the original application)."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rendered indefinite because claim 12 is written as "a method of controlling average particle size of agent containing microspheres". This claim can be interpreted in two ways: 1) a method of controlling average particle size of an agent (e.g. an antigen) that contains microspheres; or 2) a method of controlling the average

particle size of microspheres containing an agent (e.g. an antigen). Accordingly, this claim is indefinite.

For the sake of compact prosecution, claim 12 is being interpreted as a method of controlling the average particle size of microspheres that contain an agent such as an antigen.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the biodegradable polymer poly (DL-lactide-co-glycolide), does not reasonably provide enablement for all biodegradable polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide sufficient information to show that the average particle size of microspheres containing an agent and any biodegradable polymer can be controlled using the modified solvent extraction process claimed in the instant application.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of

working examples, state of the art, predictability of the art, the relative skill of those in the art, and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 12 of the instant application claims a method of controlling average particle size of agent containing microspheres comprising adjusting the viscosity of an oil, adding the oil to an emulsion containing any biodegradable polymer, a stabilizer and an agent; centrifuging the emulsion and finally removing the microspheres.

Breadth of the claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The rejected claim is extremely broad. Applicants claim that the average particle size of microspheres containing any biodegradable polymer can be controlled.

Guidance of the Specification/Working Examples: Applicants have only provided data showing the use of emulsion viscosity as a means for controlling the average particle size of polymerized lactide and glycolide microspheres. The examples shown on pages 5-11 of the instant specification provide detailed steps in producing the controlled particle size microspheres of poly (DL-lactide-co-glycolide) by the modified solvent extraction process of the present invention.

State of the Art: According to Yeh et al. (provided on IDS submitted 5/16/94), at the time of the instant invention various biodegradable polymers were investigated as possible antigen carriers, including serum albumin beads, polyacryl starch

microparticles, polyacrylamide microparticles, poly(butyl-2-cyanocrylate) nanoparticles and polylactide co-glycolide microparticles. However, problems associated with polyacrylamide and poly(butyl-2-cyanocrylate) limited the use of said polymers as antigen delivery systems (see pages 437-438). Therefore, Yeh et al. teach that although there has been some success toward the use of certain polymers such as poly (DL-lactide-co-glycolide) for vaccine delivery, this has not been true regarding the use of all other biodegradable polymers.

Predictability/Unpredictability in the Art: There is a general lack of predictability in the pharmaceutical art. In re Fisher, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970). It would be unpredictable for the skilled artisan to control the particle size of microspheres containing any biodegradable polymer as there are numerous polymers with differing characteristics and properties and not all of them have been shown to be useful in vaccine delivery (see State of the Art above).

The Quantitation of Experimentation Required: In order to practice Applicants invention, it would be necessary for one to conduct an exhaustive amount of experiments. Applicant would need to provide reasonable data showing that the size of microspheres containing polymers other than poly (DL-lactide-co-glycolide) can be controlled by applicants claimed modified solvent extraction process. Therefore, in order to practice the claimed invention, the amount of experimentation required would be considered undue and burdensome.

In conclusion, Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion"

and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable." A method of controlling particle size of microspheres containing any biodegradable polymer by the modified solvent extraction process of the present invention is not enabled by the instant specification.

Conclusions

Claims 1-15 are rejected. Claims 16-24 are canceled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1617

KRM

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617